NASA TECHNICAL TRANSLATION NASA TT F-14,821

RADIATION STERILIZATION WITH A VAN DE GRAAF ACCELERATOR

W. Jahn and M. Schinkmann

Translation of "Strahlensterilisation mit dem Van-de-Graaf-Beschleuniger", Atomwirtschaft, Vol. 17, Sep/Oct 1972, pp 527-529.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
WASHINGTON, D.C. 20546 MARCH 1973

STANDARD TITLE PAGE

1. Report No.
NASA TT F-14,821

2. Government Accession No.

3. Recipient's Catalog No.

4. Title and Subtitle
RADIATION STERILIZATION WITH A VAN DE GRAAF ACCELERATOR

5. Report Date
March 1973

6. Performing Organization Code

7. Author(s)
W. Jahn and M. Schinkmann

8. Performing Organization Report No.

9. Performing Organization Name and Address
LINGUISTIC SYSTEMS, INC.
116 AUSTIN STREET
CAMBRIDGE, MASSACHUSETTS 02139

10. Work Unit No.

11. Contract or Grant No.
~~NASW-[illegible]~~ NASW-2482

12. Sponsoring Agency Name and Address
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
WASHINGTON, D.C. 20546

13. Type of Report & Period Covered
TRANSLATION

14. Sponsoring Agency Code

15. Supplementary Notes
Translation of: "Strahlensterilisation mit dem Van-de-Graaf-Beschleuniger", Atomwirtschaft, Vol. 17, Sep/Oct 1972, pp 527-529.

16. Abstract
Radiation sterilization of medical disposable articles is one of the few areas of application for current industrial use of an energetic electron and gamma radiation. With increasing use of disposables, the method finds increasing interest. The sterilization process occurs according to statistical laws. This results in certain aspects which must be taken into consideration during application of radiation sterilization. For example, several technical and economic aspects of the procedure are detailed for an electron beam sterilization installation.

17. Key Words (Selected by Author(s))

18. Distribution Statement
UNCLASSIFIED - UNLIMITED

19. Security Classif. (of this report)
UNCLASSIFIED

20. Security Classif. (of this page)
UNCLASSIFIED

21. No. of Pages
~~8~~ 11

22. Price
$3.00

RADIATION STERILIZATION WITH A
VAN DE GRAAF ACCELERATOR

W. Jahn and M. Schinkmann†

Introduction

Industrial application of "ionizing radiation" began soon after the completed development of effective radiation sources. During the fifties, the first electron accelerators were completed in the U.S.A. for industrial use in sterilization installations. During this same decade there followed the construction of large radiation stations with radioactive radiation sources. Europe followed this example only a few years later. In the Federal Republic of Germany the first electron beam-sterilization installation became operative in 1959. In the meantime radiation sterilization has carved out a significant share of the market along side of conventional procedures. /527*

In recent years, the development of high-performance and simultaneously cheap synthetic materials, suitable for mass production, has brought about increasing use of medical disposables. The use of disposable articles is one of the essential presuppositions for the desirable improvement of individual hygiene in the medical sector. Since many effective synthetics are unsuitable for classical sterilization with hot air or with hot steam at temperatures over 100° C, the emerging trend toward disposable articles necessarily stimulates the use of radiation sterilization methods.

Biological Effectiveness of Ionizing Radiation

The expression "ionizing radiation" designates all forms of radiation which, by their large energy, are capable of ionizing neutral atoms. "Radiation" can be classified according to two

---

*Numbers in righthand margin indicate pagination in the foreign text.

†W. Jahn, Technical Asst., Dr. M. Schinkmann, Product Manager and Section Chief, Leybold-Heraus GmbH & Co., 5 Cologne 51, Bonmer Strasse 504.

physical characteristics. Thus one can distinguish particle radiation and photon radiation. The present discussion will not enter into the details of such a distinction. To the first kind belong accelerated electrons, protons, alpha particles, neutral atoms, and others. By photon radiation is understood, for example, /528
x-ray and gamma radiation. The present state of technology generally uses electron beams, x-ray beams, and gamma ray beams for purposes of industrial sterilization.

Charged particles such as electrons, for example, are surrounded by an electric field, the so-called Coloumb field. This enables them, upon entrance into materials, to interact strongly with the neighboring atoms or molecules respectively. By contrast, the probability for the appearance of corresponding interaction processes between energetic neutral particles or photons and the atoms of the irradiated material is much smaller.

In an interaction process between radiation and material, part of the radiation energy is transferred to the atom. According to the amount of energy taken up, the atom is ionized or is put into an "excited" state. The shell-electron which has been ejected from the atom through the ionization process generally has sufficient kinetic energy to subsequently ionize neighboring particles. A "primary ionization" is therefore followed by "secondary ionizations". The effect of ionizing radiation on micro-organisms is therefore largely independent of the kind of radiation used. Nevertheless, even for equal dosage, the resulting biological effect can be different because of the various dosage effects.

Destruction of micro-biological organisms by ionizing radiation follows probabilistic laws. This characteristic is shared by radiation sterilization and by conventional sterilization processes. The sterilization effect subject to statistical laws has the result that with increasing time a sample exposed to radiation treatment will with ever increasing probability have the propogation probability of organisms present in it destroyed. Absolute sterility can only be conditionally reached in this fashion. Rather, it can be shown that independent of the procedure chosen, of the magnitude of the required safety factor, and of the care with which the sterilization process is performed, there always exists a definite probability for the presence of a non-sterile article. The frequently posed demand for absolute sterility loses its meaning. Discussion of this topic must be limited to the question of what level of sterility is suitable in view of all its medical and economic aspects, and should therefore be reasonably pursued.

Inactivation Factor

One measure for the effectiveness of a sterilization procedure is the inactivation factor. This gives the reduction of the active organisms by means of the sterilization process, and is defined as the ratio of the number of vital germs after sterilization to the number of originally present vital germs.

Table 1. Reciprocal of the Inactivation Factor for Various Micro-organisms and Different Radiation Doses

Mikroorganismen Typ	1 Mrad	2 Mrad	3 Mrad	4 Mrad
Staph. Aureus	$>10^8$	—	—	—
B. Pumilius E 601	$0{,}5\cdot10^4$	$0{,}28\cdot10^8$	$>10^8$	—
B. Glob. ATCc 9372	$0{,}11\cdot10^4$	$0{,}12\cdot10^7$	$>10^8$	—
B. Subtilis	$1.0\cdot10^3$	$0{,}5\cdot10^6$	$>10^8$	—
Str. Faecium	—	$0{,}17\cdot10^1$	$0{,}25\cdot10^2$	$0{,}2\cdot10^3$
B. Stearothemoph.	—	$\sim10^3$	—	$5\cdot10^4$
B. Cereus	$0{,}2\cdot10^5$	$0{,}17\cdot10^8$	—	—
B. Pum. anaerob	—	—	10^{10}	—
Cl. Botul. Typ B	—	10^{10}	—	—

Since micro-organisms react in type-specific fashion to each sterilization process, it is necessary to know the individual inactivation factor for every process and every species. Table 1 shows the reciprocal of the inactivation factors (radiation sterilization) for different micro-organisms.

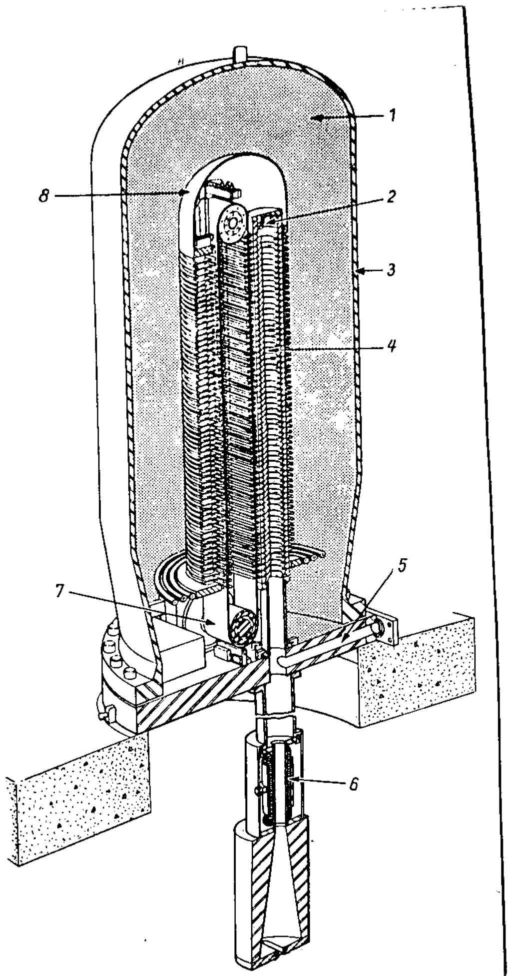


Fig. 1. Electron Accelerator.

1) isolation volume with N_2 and CO_2 gas; 2) electron source (tungsten cathode); 3) pressure chamber; 4) acceleration type; 5) evacuation studs; 6) deflection coils; 7) charged transport bend; 8) terminal

Just like the kind of sterilization process, the environment of the micro-organism can influence the effect of the process for a given sterilization procedure. This can be explained briefly by two examples:

Vegetative cells in the presence of pure oxygen react much more sensitively to radiation treatment than in a normal atmosphere. The opposite is observed when salmonella strains are subjected to a freeze-drying procedure prior to irradiation. Thus the inactivation factor appears as a function of three variables: the sterilization method, the micro-organism type, and the environmental conditions prevailing for the micro-organism during the sterilization process.

Microbiological Contamination

In the previous section it was shown that the specific inactivation factor significantly affects the effectiveness of a sterilization process. Because of this, the success of a sterilization procedure depends decisively on the precontamination of the /529
products to be sterilized. This shifts a not inconsiderable portion of the burden for sterilization upon the pre-history of the product to be sterilized. Obviously a defective hygienic production environment requires a higher safety factor for the subsequent sterilization process. The minimum dosage, the fumigation, or other parameters must always be formulated with respect to maximum contamination. Dosage and time expenditure generally determine sterilization cost, and are therefore of decisive economic significance for the process. It is therefore desirable to keep microbiological contamination as low as possible in the first place, and to choose conditions of production in such a way that this goal is optimally attained.

Economic Aspects of Sterilization Radiation

A number of economic data will be derived using as an example a radiation sterilization installation operating with high-energy electron radiation according to the Van de Graaf principle.

It will first of all be presupposed that the installation operates at a voltage of 3 mV and a radiation current of 1 mA. This gives a power output of $\dot{W}$ = 3 kW.

Omitting exceptions, the accepted surface dosage is now 2.5 mrad. Further, it shall be assumed that the entire available energy is totally absorbed on an area of 25 cm (scanning breadth) in a material of density d = 1 g/cm^3. From these values one obtains the following relations

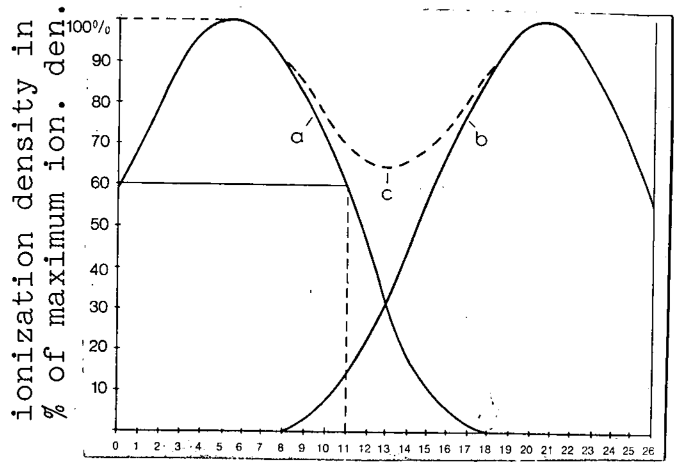
$$\dot{W} = 0.432 \cdot 10^6 \cdot 2.5 \left[\frac{\text{g mrad}}{\text{h}}\right] \qquad (1)$$

or

$$\dot{W} = 0.173 \cdot 10^5 \cdot 25 \cdot 2.5 \left[\frac{\text{g mrad}}{\text{h}}\right] \qquad (2)$$

Equation (2) says that for a power output of 3 kW a material strip of length 173 m and breadth of 25 cm can be treated with a radiation dosage of 2.5 mrad in 1 hour.

It is desired to obtain from this result estimation values from a number of objects that can be sterilized per unit time. For this further assumptions are necessary concerning the dimension and packing of these objects. Practical packing units can, for example, have dimensions of 11 cm length, 8.3 cm breadth, and 1 cm height. To completely utilize the penetration depth of the 3 meV radiation (see Fig. 2), three such packages with a total height of 3 cm should be stacked one above the other. When three packing units of three pieces each have passed the radiation field they are turned by 180° so that the bottom package is now on top and vice versa. A transport belt system brings the turned packages back again and passes them for a second time through the radiation field (compare Fig. 2, function c). In this fashion, 4719 packages can be sterilized per hour.



absorber thickness (mm) relative to a density of $1 g/cm^3$

Figure 2. Ionization density in percent of maximum ionization density of a 3 meV electron beam as a function of absorber density.

This result presupposes loss-free transmission of the sterilization power to the product to be sterilzed. In practice the transmission is connected with not inconsiderable losses. Generally the following influences must be taken into consideration qualitatively and quantitatively:

dosage inhomogeneity	≥5%
x-ray bremsstrahlung	2%
unused energy by radiation escaping beyond the edges	5%
unused energy by radiation escaping through the interstices of the stacked packages	17%
others	2%

From this there results a rough formula for the capacity of a Van de Graaf sterilization installation:

$$\dot{W}_{eff} \approx \frac{2}{3}\dot{W} \tag{3}$$

If one assumes that each package with dimensions 11 cm × 8.3 cm × × 1 cm has five elements to be sterilized (for example, syringes), then about 15,700 pieces per hour can be irradiated with 2.5 mrad surface radiation dosage and sterilized.

In particular cases improvements can be attained relative to equation (3). This is particularly true if packing units can be chosen which make possible a reduction of the losses in their interstices. Furthermore, the power output of the installation can be increased by almost 100% by increasing the radiation current. Altogether it appears that the radiation sterilization method is competitive with conventional procedures and will find increasing use in the future because of its specific advantages.

REFERENCES

1. E.C. Pöllard, Radiation in Biological Systems, Proc. Int. Conf. US Army Natick Laboratories, US Department of Commerce (1963).

2. R.I. Van de Graff, J.G. Trump, W.W. Buedmer: Electr. generations for the acceleration of charged particles, Repts. Progr. in Phys. 2(1948).

3. E.A. Burrill, A.J. Gale: Electron beams sterilize food and drugs, Electronics 25, p. 98 (1952).

4. Proceedings of Radiosterilization of Medical Products, Budapest, Isotopes and Radiation Technology 5(1), p. 84 (1967).

5. C.G. Dunn, W.L. Campbell, H. Fram and A. Hutchins: Biological and Photo-Chemical Effects of High Energy, Electrostatically Produced Roentgen Rays and Cathode Rays, Journ. Appl. Phys., Vol. 19, No. 7, pp 605-616 (July 1948).

6. The Pharmaceutical Press, London. Recent Developments in the Sterilization of Surgical Materials (1961).

7. E. Rexer and I. Wuckel: Chemische Veränderungen von Stotten durch energiereiche Strahlen, VEB Vetlag fur Grundstottindustrie, Leipzig (1965).